

Serial No.: 10/552,717
Atty. Docket No.: P70890US0

REMARKS

The Office Action mailed April 1, 2008, has been carefully reviewed and, by this Amendment, Applicant has amended claims 1-10 and added claims 11-20. Claims 1-20 are pending in the application. Claims 1, 10 and 16 are independent.

The Examiner rejected claims 1-10 under 35 U.S.C. 102(e) as being anticipated by U.S. Publication No. US 2003/0018293 to Tanghoj et al. ("Tanghoj").

As clarified in amended claim 1, the present invention is directed to a catheter assembly including a container having a cavity, at least one catheter element with a proximal end adapted for insertion into a urinary canal and an opposite distal end, and a catheter handle having a sleeve section adapted to surround a portion of the container and also being adapted to be interlocked with the catheter element. Accordingly, the catheter handle is configured to be detached from the catheter element and from the container. This is not shown by the prior art.

Tanghoj discloses a catheter kit having a first section 42 and a second section 44 that are telescopically interconnected. Prior to use, the first catheter section 42, or catheter element, is covered by a protective member 46 or container, and both the container 46 and the catheter element 42 are contained within the

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second section 44 which can act as a handle. To use the catheter device, the container 46 and catheter element 42 are extracted from the handle 44 until a fully extracted position is reached as shown in Figure 17. In the fully extracted position, protrusions 47 on the container 46 lock into engagement with the seal 50 on the catheter element, after which the container 46 is removed just prior to use (see paragraph [0094]). Hence, the handle 44 remains attached to the container 46 both in the compact storage position shown in Figure 16 and while the container 46 and catheter element 42 are being extracted as shown in Figure 17; movement from one configuration to the next does not include detachment of the handle. And significantly, *at no time* is the handle 44 *detached* from the catheter element 42.

Furthermore, the catheter element 42 of Tanghoj is configured so as *not* to be detached from the handle. The seal 50 on the distal end of the catheter element 42 has a groove 51 formed therein that captures the flange 45 on the proximal end of the handle 44 when in the extracted position, effectively preventing further movement of the handle 44 in either direction relative to the catheter element 42. This fixation and prevention of further movement is necessary so that, when the device reaches the position shown in Figure 17 with the protrusions 47 locked onto the seal 50,

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the container 46 can nonetheless be pulled away and removed for use of the catheter without pulling the catheter element out with it. *By no means is removal of the handle contemplated or desired.* Quite the opposite.

In the present invention, on the other hand, the handle is first positioned over the container in the storage configuration shown in Figures 1 and 2. To use the catheter, the handle is *detached or removed* from the container and from the catheter element held therein, and then reattached to the distal end of the catheter element, as shown in Figure 3. Finally, the container is removed for use of the catheter, as depicted in Figure 4. This structure as set forth in claim 1 is not anticipated or suggested by Tanghoj but is patentable thereover.

For at least the same reasons, claim 10 directed to a method of preparing a catheter device is also patentable over the prior art. Specifically, claim 10 includes the steps of, beginning with the catheter handle sleeve section surrounding a portion of the container, *detaching* the catheter handle from the container assembly and from the catheter element, and then connecting the catheter handle to the catheter element in a different position from that in which the sleeve section surrounded the container. Finally, the container is removed to expose the catheter element.

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But the step of *detaching* the catheter handle from both the container assembly and from the catheter element is not shown in or suggested by Tanghoj.

Finally, new claim 16 is also in condition for allowance for the same reasons already discussed and further as explicitly setting forth that the catheter handle is adapted to adopt two different configurations. In the first configuration, the handle is attached to the container assembly with the sleeve section surrounding a portion of the container (see Figure 2). In the second configuration, the handle is interlocked with the catheter element in a substantially linear arrangement therewith (see Figure 4). To move the catheter handle from the first to the second configuration, the catheter handle is configured to be physically detached so as to be entirely separate from the catheter element and from the container.

For at least the foregoing reasons, claims 1, 10 and 16 are patentable over the prior art. Favorable reconsideration and allowance thereof, along with claims 2-9, 11-15 and 17-20 dependent thereon, is requested.

Particularly with reference to claims 15 and 18, the prior art does not teach or suggest that the distal section of the catheter element has at least one protruding part and the proximal

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compartment of compartment cavity is adapted to accommodate a proximal section of the catheter, with the distal end of the sleeve section being smaller in diameter than the protruding part of the catheter element and *being adjacent the proximal side of the protruding part in the first configuration and adjacent the distal side of the protruding part in the second configuration.*

With this response, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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